REMARKS

Applicants respectfully request reconsideration of the present Application. Claims 1, 2 and 6 have been amended herein. Claims 3-5 have been cancelled. A request for continued examination is being filed herewith.

Rejections based on 35 U.S.C. § 112

Claims 1-2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 stands rejected as being vague and indefinite because the comparison step is directed to monitoring inflammatory bowel disease in a patient but the preamble merely measures the concentration of total lactoferrin. Applicants have amended the preamble and request withdrawal of the rejection of claim 1.

Claim 1 stands rejected as the comparison step is vague and indefinite because it recites "the patient" and "treatment". Applicants have amended claim 1 to provide proper antecedent basis. As such, Applicants request withdrawal of the rejection of claim 1.

Claims 3-5 (Claim 3 and its dependent claims 4-5) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Claims 3-5 have been cancelled. As such, Applicants request withdrawal of this rejection.

Rejections based on 35 U.S.C. § 102

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdeggal Brothers v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the . . .

claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 2 USPQ 2d 1913, 1920 (Fed. Cir. 1989). See also, MPEP § 2131.

Claim 6 stands rejected under 35 U.S.C. 102(e) as being anticipated by Hayes et al. (US Patent No. 6,358,939 B1). As the Hayes reference fails to describe, either expressly or inherently, each and every element as set forth in the rejected claim, Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claim 6, recites a method for monitoring a patient having inflammatory bowel disease. The method of claim 6 comprises obtaining a first fecal sample from a human with inflammatory bowel disease at a first time, determining the concentration of endogenous lactoferrin in the first fecal sample to obtain a first lactoferrin concentration, obtaining a second fecal sample from the human with inflammatory bowel disease at a second time after treatment of the human's inflammatory bowel disease later than the first time, determining the concentration of endogenous lactoferrin in the second sample to obtain a second lactoferrin concentration, and comparing the first lactoferrin concentration to the second lactoferrin concentration to monitor the inflammatory bowel disease activity of the human and determine whether treatment of the inflammatory bowel disease has been effective in decreasing or eliminating gastrointestinal inflammation.

By way of contrast, the Hayes reference discloses a method for treating dextran sulfate induced inflammatory bowel disease in mice with calcitriol. The Hayes reference, however, does not describe, either expressly or inherently, a method for monitoring a human having inflammatory bowel disease which includes obtaining a first fecal sample from a human at a first time and obtaining a second fecal sample from the same human after treatment of the human's inflammatory bowel disease at a second time later than the first time, determining the

concentration of the first sample and the second sample and comparing the first lactoferrin concentration to the second lactoferrin concentration to monitor the inflammatory bowel disease activity of the human and determine whether treatment of the inflammatory bowel disease has been effective in decreasing or eliminating gastrointestinal inflammation as recited in the method of independent claim 6. The method taught by Hayes is limited to testing fecal samples from mice with chemically-induced IBD for lactoferrin. Applicants submit that the method for determining whether lactoferrin levels have reduced due to treatment in a human is not discussed. Rather, Hayes states "[a] patient with symptoms of IBD is administered an effective dose of calcitriol daily until symptoms of IBD are reduced." Thus, in humans, Hayes discusses determining whether calcitriol has been effective by determining if symptoms of IBD are reduced, not fecal lactoferrin. There is no discussion of comparing the first lactoferrin concentration from a human fecal sample for a person to a second lactoferrin concentration of a human fecal sample from the same person to monitor the inflammatory bowel disease activity of the person and determine whether treatment of the inflammatory bowel disease has been effective in decreasing or eliminating gastrointestinal inflammation as recited in claim 6.

As such, it is respectfully submitted that the Hayes reference fails to describe, either expressly or inherently, each and every element of independent claim 6. Accordingly, claim 6 is not anticipated by the Hayes reference and withdrawal of the 35 U.S.C. §102(b) rejection of this claim is requested.

Rejections based on 35 U.S.C. § 103

Claim 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes et al. (US Patent No. 6,358,939 B1) in view of Uchida et al. (US Patent No. 5,552,292). "). As

the Hayes reference in view of the Uchida reference fail teach or suggest all the limitations of the rejected claims, Applicants respectfully traverse this rejection, as hereinafter set forth.

Independent claim 1, as amended, is directed to method for monitoring a person having inflammatory bowel disease. A first human fecal sample from a person is obtained and the concentration of lactoferrin the first human fecal sample is determined. The first fecal sample is diluted. The first sample is contacted with immobilized polyclonal antibodies to endogenous lactoferrin to create a first treated sample. The first treated sample is contacted with enzyme-linked polyclonal antibodies to create a first readable sample. The optical density of said first readable sample is determined at 450nm. A purified lactoferrin standard curve is generated and a linear portion of the standard curve is determined. The optical density of said first readable sample is compared to said standard curve to determine a concentration of the first diluted sample and to determine whether the concentration of the first diluted sample is within the linear portion of the standard curve. If the first diluted sample is within the linear portion of the standard curve, the concentration of total endogenous lactoferrin in said first fecal sample is determined.

A second human fecal sample from the same person is obtained at a time after the first sample was obtained and the concentration of lactoferrin in the second human fecal sample is determined. The lactoferrin concentration of the first fecal sample is compared to the lactoferrin concentration of the second sample for the person to monitor the inflammatory bowel disease activity of the person and determine if the person has had a decrease or increase in gastrointestinal inflammation.

By way of contrast, the Hayes reference discloses a method for treating dextran sulfate induced inflammatory bowel disease in mice with calcitriol. The Hayes reference,

however, does not describe, either expressly or inherently, a method for monitoring a human having inflammatory bowel disease which includes obtaining a first fecal sample from a human at a first time and obtaining a second fecal sample after treatment of the human's inflammatory bowel disease at a second time later from the same human than the first time, determining the concentration of the first sample and the second sample and comparing the first lactoferrin concentration to the second lactoferrin concentration to monitor the inflammatory bowel disease activity of the human and determine if person has had an increase or decrease in gastrointestinal inflammation as recited in the method of independent claim 1. The method taught by Hayes is limited to testing fecal samples from mice with chemically-induced IBD for lactoferrin. Applicants submit that the method for determining whether lactoferrin levels have reduced due to treatment in a human is not discussed. Rather, Hayes states "[a] patient with symptoms of IBD is administered an effective dose of calcitriol daily until symptoms of IBD are reduced." Thus, in humans, Hayes discusses determining whether calcitriol has been effective by determining if symptoms of IBD are reduced, not fecal lactoferrin. There is no discussion of comparing the first lactoferrin concentration from a human fecal sample for a person to a second lactoferrin concentration of a human fecal sample from the same person to monitor the inflammatory bowel disease activity of the person and determine if the person has had a decrease or increase in gastrointestinal inflammation as recited in independent claim 1.

Likewise, the Uchida reference fails to teach or suggest all the limitations of the rejected claims. The Uchida reference discloses a method for diagnosing gastrointestinal tract disorders, particularly colorectal cancer, by measurement of the level of lactoferrin "in feces by immunoassay and by measurement of the level of whole-sized lactoferrin by immunoassay utilizing monoclonal antibody." Uchida reference at col. 1, lines 10–19. The Uchida reference

does not compare the lactoferrin concentration of a first fecal sample with the lactoferrin concentration of a second sample for the same person to whether the person with inflammatory bowel disease has had an increase or decrease in gastrointestinal inflammation.

As such, it is submitted that the Hayes reference in view of the Uchida reference fails teach or suggest all the limitations of the rejected claims, Accordingly, independent claim 1 is not anticipated by the Hayes reference in view of the Uchida reference and withdrawal of the 35 U.S.C. §102(b) rejection of this claim is requested. As claim 2 depends directly from claim 1, applicants request withdrawal of the §102(b) rejection of this claim as well.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Uchida et al. (US Patent No 5,552,292) in view Foster et al. (U.S. Patent No 4,444,879). Applicants have cancelled claims 3-5 and request that the rejection be withdrawn.

CONCLUSION

For at least the reasons stated above, claims 1-2 and 6 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or jdickman@shb.com (such communication via email is herein expressly granted) – to resolve the same. It is believed that no fee is due, however, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112.

Respectfully submitted,

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